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QUEEN THOMAS — Printed Name

Queen Thomas — Signature

REISSUE PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of U.S. Patent No. 5,910,319		
Applicants:	Anderson, et al.	Group Art Unit: Unassigned
Application No.:	Unassigned	Examiner: Unassigned
Filed:	January 28, 2002	
For:	FLUOXETINE ENTERIC PELLETS AND METHODS FOR THEIR PREPARATION AND USE	
Docket No.:	X-10709B	

PRELIMINARY AMENDMENT PURSUANT TO 37 C.F.R. § 1.173(b)(2)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a preliminary amendment accompanying an application for reissue of United States Letters Patent No. 5,910,319, to Neil R. Anderson, Roger G. Harrison, Daniel F. Lynch, and Peter L. Oren, and assigned of record to Eli Lilly and Company. Prior to examination of the above-identified application, entry of the following preliminary amendments is respectfully requested.

AMENDMENTS

IN THE CLAIMS:

Please cancel claims 1-18 inclusive.

Please amend the claims as follows:

19. (Amended) A formulation of [Claim 1 containing]sufficient enteric fluoxetine pellets to administer[20-100]60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

20. (Amended) A formulation of Claim 19 [containing]administering about 80-90 mg base equivalent of fluoxetine.

21. (Amended) A formulation of Claim 19 [containing]administering about 90 mg of base equivalent of fluoxetine.

25. (Amended) A gelatin capsule containing sufficient enteric fluoxetine pellets to administer a dose of 60-120 mg base equivalents of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients [the formulation of Claim 1].

26. (Amended) A gelatin capsule [containing the formulation]of Claim [24]25, wherein about 80-90 base equivalents of fluoxetine are administered.

27. (Amended) A formulation of Claim 19 containing the following:

Cores	
Sucrose - starch nonpareils, 30-35 mesh	100-150 mg
Fluoxetine layer	
Fluoxetine hydrochloride	100.5-100.8 mg
Sucrose	20-30 mg
Hydroxypropylmethylcellulose	10-15 mg
Separating layer	
Hydroxypropylmethylcellulose	4-12 mg
Sucrose	15-35 mg
Talc, 500 mesh	25-60 mg
Enteric layer	
HPMCAS-LF	60-90 mg
Triethyl citrate	10-20 mg
Talc, 500 mesh	15-25 mg
Finishing layer	
Color mixture white (HPMC + titanium dioxide)35-55 mg	
HPMC	5-15 mg
Talc	Trace.

28. (Amended) A gelatin capsule [containing the formulation] of Claim [24]25, wherein about 90 mg base equivalent of fluoxetine are administered.

29. (Amended) A formulation according to Claim 19 wherein the formulation additionally contains pindolol.

30. (Amended) A method of treating [people]a patient suffering from depression, obsessive-compulsive disorder, bulimia, pain, obsessive-compulsive personality disorder, post-traumatic stress disorder, hypertension, atherosclerosis, anxiety, anorexia nervosa, panic, social phobia, stuttering, sleep disorders, chronic fatigue, Alzheimer's disease, alcohol abuse, appetite disorders, weight loss, agoraphobia, improving memory, amnesia, smoking

cessation, nicotine withdrawal syndrome symptoms, disturbances of mood and/or appetite associated with pre-menstrual syndrome, depressed mood and/or carbohydrate craving associated with pre-menstrual syndrome, disturbances of mood, disturbances of appetite or disturbances which contribute to recidivism associated with nicotine withdrawal, circadian rhythm disorder, borderline personality disorder, hypochondriasis, pre-menstrual syndrome (PMS), late luteal phase dysphoric disorder, pre-menstrual dysphoric disorder, trichotillomania, symptoms following discontinuation of other antidepressants, aggressive/intermittent explosive disorder, compulsive gambling, compulsive spending, compulsive sex, psychoactive substance use disorder, sexual disorder, schizophrenia, premature ejaculation, or psychiatric symptoms selected from stress, worry, anger, rejection sensitivity, and lack of mental or physical energy comprising administering a formulation of Claim 19.

31. (Amended) A method of Claim 30 employing a formulation [containing 20-100] administering about 80-90 mg base equivalent of fluoxetine.

32. (Amended) A method of Claim 30 employing a formulation [containing]administering about 90 mg base equivalent of fluoxetine.

37. (Amended) A method of Claim 30 of treating [people]a patient suffering from pain, further comprising the coadministration of morphine, codeine or dextropropoxyphene.

38. (Amended) A method of Claim 37 employing a formulation [containing about 20-100]administering about 80-90 mg base equivalent of fluoxetine.

39. (Amended) A method of Claim 37 employing a formulation [containing]administering about 90 mg base equivalent of fluoxetine.

Please add new claims 40-75.

40. (New) A formulation of Claim 19, wherein the pellets further comprise a separating layer.

41. (New) A formulation of Claim 40, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

42. (New) A formulation of Claim 19, wherein the pellets further comprise a finishing layer.

43. (New) A formulation of Claim 40, wherein the pellets further comprise a finishing layer.

44. (New) A formulation of Claim 41, wherein the pellets further comprise a finishing layer.

45. (New) A formulation of Claim 21, wherein the pellets further comprise a separating layer.

46. (New) A formulation of Claim 45, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

47. (New) A formulation of Claim 21, wherein the pellets further comprise a finishing layer.

48. (New) A formulation of Claim 45, wherein the pellets further comprise a finishing layer.

49. (New) A formulation of Claim 46, wherein the pellets further comprise a finishing layer.

50. (New) A gelatin capsule of Claim 25, wherein the pellets further comprise a separating layer.

51. (New) A gelatin capsule of Claim 50, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

52. (New) A gelatin capsule of Claim 25, wherein the pellets further comprise a finishing layer.

53. (New) A gelatin capsule of Claim 50, wherein the pellets further comprise a finishing layer.

54. (New) A gelatin capsule of Claim 51, wherein the pellets further comprise a finishing layer.

55. (New) A gelatin capsule of Claim 28, wherein the pellets further comprise a separating layer.

56. (New) A gelatin capsule of Claim 55, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

57. (New) A gelatin capsule of Claim 28, wherein the pellets further comprise a finishing layer.

58. (New) A gelatin capsule of Claim 55, wherein the pellets further comprise finishing layer.

59. (New) A gelatin capsule of Claim 56, wherein the pellets further comprise a finishing layer.

60. (New) A method of Claim 30, wherein the pellets further comprise a separating layer.

61. (New) A method of Claim 60, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

62. (New) A method of Claim 30, wherein the pellets further comprise a finishing layer.

63. (New) A method of Claim 60, wherein the pellets further comprise a finishing layer.

64. (New) A method of Claim 61, wherein the pellets further comprise a finishing layer.

65. (New) A method of Claim 32, wherein the pellets further comprise a separating layer.

66. (New) A method of Claim 65, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

67. (New) A method of Claim 32, wherein the pellets further comprise a finishing layer.

68. (New) A method of Claim 65, wherein the pellets further comprise a finishing layer.

69. (New) A method of Claim 66, wherein the pellets further comprise a finishing layer.

70. (New) A method of Claim 30 without an increase in nausea.

71. (New) A method of Claim 32 without an increase in nausea.

72. (New) A method of Claim 36 without an increase in nausea.

73. (New) A method of Claim 37 without an increase in nausea.

74. (New) A method of Claim 38 without an increase in nausea.

75. (New) A method of Claim 39 without an increase in nausea.

REMARKS

Attached herewith, pursuant to 37 C.F.R. § 1.173(c), is a chart, at Appendix A, providing the status of all patent claims and of all added claims. Further included in the chart, pursuant to 37 C.F.R. § 1.173(c), is an indication of the passages in the originally filed application where, at the very least, the claims find support. In addition, a clean set of all pending claims original, amended and newly added, are provided for the convenience of the Examiner at Appendix B. It is respectfully submitted that entry of the amendments submitted herewith introduce no new matter to the reissue application.

It is respectfully submitted that the reissue application is now in order for allowance.

Respectfully submitted,

Robert D. Titus
Attorney for Applicants
Registration No. 40,206
Telephone No. (317) 277-3729

Eli Lilly and Company
Patent Division/RDT
Lilly Corporate Center
Indianapolis, Indiana 46285

January 28, 2002

APPENDIX A –

STATUS OF CLAIMS AND SUPPORT FOR CLAIM CHANGES PURSUANT TO 37 C.F.R. § 1.173(c)

Claim	Status	Indication of Support in the Disclosure
1	cancelled	
2	cancelled	
3	cancelled	
4	cancelled	
5	cancelled	
6	cancelled	
7	cancelled	
8	cancelled	
9	cancelled	
10	cancelled	
11	cancelled	
12	cancelled	
13	cancelled	
14	cancelled	
15	cancelled	
16	cancelled	
17	cancelled	
18	cancelled	
19	pending	Original patent claim drafted independent form excluding optional separating layer (column 5, lines 40-42) and optional finishing layer (column 8, lines 54-57) and incorporating dosage range(column 2, lines 17-18; column 12, lines 47, 50, 52, and 66).
20	pending	Original patent claim amended to change dependency from

		cancelled Claim 1 to Claim 19, term "containing" replaced with term "administering" (column 3, lines 61-63).
21	pending	Original patent claim amended to change dependency from cancelled Claim 1 to Claim 19, term "containing" replaced with term "administering" (column 3, lines 61-63).
22	pending	Original patent claim
23	pending	Original patent claim
24	pending	Original patent claim
25	pending	Original patent claim amended to independent form excluding optional separating layer (column 5, lines 40-42) and optional finishing layer (column 8, lines 54-57) and incorporating dosage range(column 2, lines 17-18; column 12, lines 47, 50, 52, and 66; column 3, lines 61-66).
26	pending	Original patent claim amended to reflect change in dependency from Claim 24 to Claim 25, and to incorporate a dosage range (column 3, line 64).
27	pending	Original patent claim amended to reflect change in dependency from cancelled Claim 1 to Claim 19.
28	pending	Original patent claim amended to reflect change in dependency from Claim 24 to Claim 25, and to incorporate a dosage range (column 12, lines 51 and 53).
29	pending	Original patent claim amended to reflect change in dependency from cancelled Claim 1 to Claim 19.
30	pending	Original patent claim amended to reflect change in dependency from cancelled Claim 1 to Claim 19, and to replace the term "people" with the term "a patient" (column 12, lines 41-46).
31	pending	Original patent claim amended to correct dosage range (column 3, line 64) and to replace the term "containing" with the term "administering" (column 3, lines 61-63).
32	pending	Original patent claim amended to correct dosage range

		(column 12, lines 51 and 53) and to replace the term "containing" with the term "administering" (column 3, lines 61-63).
33	pending	Original patent claim
34	pending	Original patent claim
35	pending	Original patent claim
36	pending	Original patent claim
37	pending	Original patent claim amended to replace the term "people" with the term "a patient" (column 12, lines 41-46).
38	pending	Original patent claim amended to correct dosage range (column 3, line 64) and to replace the term "containing" with the term "administering" (column 3, lines 61-63).
39	pending	Original patent claim amended to replace the term "containing" with the term "administering" (column 3, lines 61-63).
40	pending	Column 5, lines 40-42.
41	pending	Column 5, lines 58-67.
42	pending	Column 8, lines 54-57.
43	pending	Column 8, lines 54-57.
44	pending	Column 8, lines 54-57.
45	pending	Column 5, lines 40-42.
46	pending	Column 5, lines 58-67.
47	pending	Column 8, lines 54-57.
48	pending	Column 8, lines 54-57.
49	pending	Column 8, lines 54-57.
50	pending	Column 5, lines 40-42.
51	pending	Column 5, lines 58-67.
52	pending	Column 8, lines 54-57.
53	pending	Column 8, lines 54-57.
54	pending	Column 8, lines 54-57.

55	pending	Column 5, lines 40-42.
56	pending	Column 5, lines 58-67.
57	pending	Column 8, lines 54-57.
58	pending	Column 8, lines 54-57.
59	pending	Column 8, lines 54-57.
60	pending	Column 5, lines 40-42.
61	pending	Column 5, lines 58-67.
62	pending	Column 8, lines 54-57.
63	pending	Column 8, lines 54-57.
64	pending	Column 8, lines 54-57.
65	pending	Column 5, lines 40-42.
66	pending	Column 5, lines 58-67.
67	pending	Column 8, lines 54-57.
68	pending	Column 8, lines 54-57.
69	pending	Column 8, lines 54-57.
70	pending	Column 2, lines 12-16.
71	pending	Column 2, lines 12-16.
72	pending	Column 2, lines 12-16.
73	pending	Column 2, lines 12-16.
74	pending	Column 2, lines 12-16.
75	pending	Column 2, lines 12-16.

APPENDIX B – CLEAN SET OF ALL PENDING CLAIMS

19. A formulation of sufficient enteric fluoxetine pellets to administer 60-120 mg base equivalent of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

20. A formulation of Claim 1 administering about 80-90 mg base equivalent of fluoxetine.

21. A formulation of Claim 1 administering about 90 mg of base equivalent of fluoxetine.

22. A formulation of Claim 19 wherein the fluoxetine is present as fluoxetine hydrochloride.

23. A formulation of Claim 20 wherein the fluoxetine is present as fluoxetine hydrochloride.

24. A formulation of Claim 21 wherein the fluoxetine is present as fluoxetine hydrochloride.

25. A gelatin capsule containing sufficient enteric fluoxetine pellets to administer a dose of 60-120 mg base equivalents of fluoxetine, wherein the pellets comprise a core consisting of fluoxetine and one or more pharmaceutically acceptable excipients and an enteric layer comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS) and one or more pharmaceutically acceptable excipients.

26. A gelatin capsule of Claim 25, wherein about 80-90 base equivalents of fluoxetine are administered.

27. A formulation of Claim 19 containing the following:

Cores

Sucrose - starch nonpareils, 30-35 mesh	100-150 mg

Fluoxetine layer

Fluoxetine hydrochloride	100.5-100.8 mg
Sucrose	20-30 mg
Hydroxypropylmethylcellulose	10-15 mg

Separating layer

Hydroxypropylmethylcellulose	4-12 mg
Sucrose	15-35 mg
Talc, 500 mesh	25-60 mg
Enteric layer	
HPMCAS-LF	60-90 mg
Triethyl citrate	10-20 mg
Talc, 500 mesh	15-25 mg
Finishing layer	
Color mixture white (HPMC + titanium dioxide)	35-55 mg
HPMC	5-15 mg
Talc	Trace.

28. A gelatin capsule of Claim 25, wherein about 90 mg base equivalent of fluoxetine are administered.

29. A formulation according to Claim 19 wherein the formulation additionally contains pindolol.

30. A method of treating a patient suffering from depression, obsessive-compulsive disorder, bulimia, pain, obsessive-compulsive personality disorder, post-traumatic stress disorder, hypertension, atherosclerosis, anxiety, anorexia nervosa, panic, social phobia, stuttering, sleep disorders, chronic fatigue, Alzheimer's disease, alcohol abuse, appetite disorders, weight loss, agoraphobia, improving memory, amnesia, smoking cessation, nicotine withdrawal syndrome symptoms, disturbances of mood and/or appetite associated with pre-menstrual syndrome, depressed mood and/or carbohydrate craving associated with pre-menstrual syndrome, disturbances of mood, disturbances of appetite or disturbances which contribute to recidivism associated with nicotine withdrawal, circadian rhythm disorder, borderline personality disorder, hypochondriasis, pre-menstrual syndrome (PMS), late luteal phase dysphoric disorder, pre-menstrual dysphoric disorder, trichotillomania, symptoms following discontinuation of other antidepressants, aggressive/intermittent explosive disorder, compulsive gambling, compulsive spending, compulsive sex, psychoactive substance use disorder, sexual disorder, schizophrenia, premature ejaculation, or psychiatric symptoms selected from stress, worry, anger, rejection sensitivity, and lack of mental or physical energy comprising administering a formulation of Claim 19.

31. A method of Claim 30 employing a formulation administering about 80-90 mg base equivalent of fluoxetine.

32. A method of Claim 30 employing a formulation administering about 90 mg base equivalent of fluoxetine.

33. A method of Claim 30 wherein the fluoxetine is present as fluoxetine hydrochloride.

34. A method of Claim 31 wherein the fluoxetine is present as fluoxetine hydrochloride.

35. A method of Claim 32 wherein the fluoxetine is present as fluoxetine hydrochloride.

36. A method of Claim 30 employing a formulation containing the following:

Cores	
Sucrose - starch nonpareils, 30-35 mesh	100-150 mg
Fluoxetine layer	
Fluoxetine hydrochloride	100.5-100.8 mg
Sucrose	20-30 mg
Hydroxypropylmethylcellulose	10-15 mg
Separating layer	
Hydroxypropylmethylcellulose	4-12 mg
Sucrose	15-35 mg
Talc, 500 mesh	25-60 mg
Enteric layer	
HPMCAS-LF	60-90 mg
Triethyl citrate	10-20 mg
Talc, 500 mesh	15-25 mg
Finishing layer	
Color mixture white (HPMC + titanium dioxide)35-55 mg	
HPMC	5-15 mg
Talc	Trace.

37. A method of Claim 30 of treating a patient suffering from pain, further comprising the coadministration of morphine, codeine or dextropropoxyphene.

38. A method of Claim 37 employing a formulation administering about 80-90 mg base equivalent of fluoxetine.

39. A method of Claim 37 employing a formulation administering about 90 mg base equivalent of fluoxetine.

40. A formulation of Claim 19, wherein the pellets further comprise a separating layer.

41. A formulation of Claim 40, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

42. A formulation of Claim 19, wherein the pellets further comprise a finishing layer.

43. A formulation of Claim 40, wherein the pellets further comprise a finishing layer.

44. A formulation of Claim 41, wherein the pellets further comprise a finishing layer.

45. A formulation of Claim 21, wherein the pellets further comprise a separating layer.

46. A formulation of Claim 45, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

47. A formulation of Claim 21, wherein the pellets further comprise a finishing layer.

48 A formulation of Claim 45, wherein the pellets further comprise a finishing layer.

49. A formulation of Claim 46, wherein the pellets further comprise a finishing layer.

50. A gelatin capsule of Claim 25, wherein the pellets further comprise a separating layer.

51. A gelatin capsule of Claim 50, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

52. A gelatin capsule of Claim 25, wherein the pellets further comprise a finishing layer.

53. A gelatin capsule of Claim 50, wherein the pellets further comprise a finishing layer.

54. A gelatin capsule of Claim 51, wherein the pellets further comprise a finishing layer.

55. A gelatin capsule of Claim 28, wherein the pellets further comprise a separating layer.

56. A gelatin capsule of Claim 55, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

57. A gelatin capsule of Claim 28, wherein the pellets further comprise a finishing layer.

58. A gelatin capsule of Claim 55, wherein the pellets further comprise finishing layer.

59. A gelatin capsule of Claim 56, wherein the pellets further comprise a finishing layer.

60. A method of Claim 30, wherein the pellets further comprise a separating layer.

61. A method of Claim 60, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

62. A method of Claim 30, wherein the pellets further comprise a finishing layer.

63. A method of Claim 60, wherein the pellets further comprise a finishing layer.

64. A method of Claim 61, wherein the pellets further comprise a finishing layer.

65. A method of Claim 32, wherein the pellets further comprise a separating layer.

66. A method of Claim 65, wherein the separating layer comprises a non-reducing sugar and one or more pharmaceutically acceptable excipients.

67. A method of Claim 32, wherein the pellets further comprise a finishing layer.

68. A method of Claim 65, wherein the pellets further comprise a finishing layer.

69. A method of Claim 66, wherein the pellets further comprise a finishing layer.

70. A method of Claim 30 without an increase in nausea.

71. A method of Claim 32 without an increase in nausea.

72. A method of Claim 36 without an increase in nausea.

73. A method of Claim 37 without an increase in nausea.

74. A method of Claim 38 without an increase in nausea.

75. A method of Claim 39 without an increase in nausea.